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Shape of Change in Internet Based Behavioral Activation Treatment for Depression

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Introduction

Despite the efficacy of treatments for depression, the global burden of depression is unremitting. Depression is predicted to be the 2nd leading cause of disability by 2020 (Murray & Lopez, 1997). However, in industrialised countries, only 35-50% of individuals will receive treatment. Rates of help-seeking are even lower in specific sub-populations of individuals suffering from depression (e.g., perinatal 15-30%, O'Mahen et al. 2009). Further, of those that do receive treatment, only 50-60% will recover. Accessible, efficacious, efficient treatments are needed to improve rates of both treatment receipt and response.

Remotely based treatments, which are often delivered in a more anonymous format that may be more acceptable to individuals worried about mental health stigma, and are widely available across broad geographic locations, are one option to addressing this problem. However, although a number of meta-analyses have demonstrated that remote forms of treatment delivery produce similar effect sizes to face-to-face treatments (Andrews et al. 2010), recent meta-analyses have demonstrated that the effects of remotely based treatments may not be as enduring as face-to-face treatments, and there is some evidence that this may be particularly true when therapist input is not provided alongside the online content (Mogoase et al. 2016). Efforts to explore the reasons for these results are needed.

Therapy process research has the potential to examine the mechanisms through which therapies work and have lasting effects. In doing so, it may inform efforts to improve the efficacy and efficiency of treatment (Lorenzo-Luaces, German, & DeRubeis, 2015). By isolating specific therapeutic processes that support client change, treatments could be streamlined to focus on particularly effective elements of treatment. This may reduce dropout and maximise the probability of client change.

One approach to accomplishing this goal is to examine trajectories of symptom change and pinpoint either upwards or downwards shifts in symptoms in an effort to highlight

key moments of change. This trajectory approach has been used successfully in other studies of CBT for both anxiety and depression (Aderka, Nickerson, Bøe, & Hofmann, 2012; Hayes, Yasininski, Ben Barnes, & Bockting, 2015; Vittengl, Clark, Thase, & Jarrett, 2013). At least three trajectories of change have been identified: linear, quadratic, and cubic (Hayes, Laurenceau, Feldman, Strauss, & Cardaciotto, 2007). Within these patterns, two specific moments of change have been identified in the therapy process literature that are of interest for this paper: sudden gains and depression spikes.

Sudden Gains. In a seminal paper, Tang and DeRubeis (1999) demonstrated that up to (39%) of individuals receiving CBT for depression experienced a sudden gain, defined as a large and stable drop in symptoms from one session to the next, and typically occurring early in treatment. Sudden gains were associated with better symptom improvement at the end of treatment compared to those without sudden gains, and were preceded by change in cognitions. Other studies of CBT have failed to find a relationship between cognitions and sudden gains, even when the sudden gain was related to better outcome (Kelly, Roberts, Ciesla, 2005). Subsequent studies have also found evidence of sudden gains with associated improved therapeutic improvement across a range of other treatments, such as supportive expressive (SE) therapy (Tang, Luborsky, and Andrusyna. 2002), face-to-face behavioral activation (BA; (Hopko, Robertson, & Carvalho, 2009; Hunnicutt-Ferguson, Hoxha, & Gollan, 2012), general psychotherapy for depression (Kelly, Cyranowski,&Frank, 2007) and CBT for recurrent depression (Abel, Hayes, Henley, & Kuyken, 2016). However, other studies have failed to find an association between sudden gains and outcome in both IPT (Kelly, Cyranowski & Frank, 2007) and CBT (Ryan, 2013). At the client level, it is as yet unclear whether client or therapist factors are associated with sudden gains. Critically, both therapist interpretation accuracy and case conceptualization have been found to be related to sudden gains in CBT and SE therapy (Abel et al., 2017; Aderka et al. 2012). It is unclear

whether these factors are both necessary and sufficient to produce a sudden gain. Further, it is not yet known if internet-based treatments, which have less therapist contact time and less of an emphasis on case conceptualisation, will produce sudden gains. Likewise, it is unclear if the limited time therapists have to act in internet-based treatments renders those actions more potent. Indeed, only one study has investigated sudden gains in a remotely delivered treatment. That study found evidence of sudden gains in a CBT treatment for health anxiety; those with sudden gains had better clinical outcomes than those without sudden gains and those with gradual gain patterns (Hedman et al. 2014). Neither client nor therapist factors were examined in that study. There has been no study we are aware of that has examined these factors in an internet-based treatment for depression.

Depression Spikes. Depression spikes are a temporary increase in distress that theoretically occur when individuals confront depressive thoughts and emotions they previously avoided. Depression spikes are conceptually similar to the relatively short-lived increases in distress that occur during exposure in treatments for anxiety disorders (Hayes, Feldman, Beevers, Laurenceau, Cardaciotto, et al., 2007). Depression spikes have been linked to improved symptom outcome in a CBT-based treatment that involved emotional exposure approaches to depressogenic material (Hayes et al., 2005; 2007). In that trial, a cubic pattern of change that was characterised by a rapid early improvement in symptoms, followed by a transient increase (spike) in symptoms during the exposure-based portion of the treatment. Both the early drop in symptoms and the spike predicted better treatment responses. This cubic pattern of change has been replicated in two other trials of this exposure-based cognitive therapy for depression (Grosse-Holtforth et al., 2012; Grosse-Holtforth et al., 2016). However, it is unclear whether intensive client processing is necessary to produce a therapeutic depressive spike, or if a treatment (such as Behavioural Activation) that involves

experientially approaching avoided behaviours will also create depression spikes that are related to improved symptom outcomes.

The Current Study

In this study, we aimed to examine which trajectories of change characterised an internet-based Behavioral Activation (BA) treatment for postpartum depression (PPD). Identifying whether a specific trajectory of change characterises a particular treatment (i.e., BA) can help to identify discontinuities where change occurs and the processes associated with that change. We therefore also sought to examine whether sudden gains and depression spikes that are associated with different trajectories of change predicted better depression outcomes. By identifying overall trajectories, it may also be possible to compare patterns of change across treatments.

Because previous literature has found sudden gains are present in and predict better outcomes in BA and an online treatment for health anxiety (Hunnicutt-Ferguson et al. 2012; Masterson et al. 2014, Hedman et al. 2014), we hypothesized that a quadratic trajectory of change characterised by early improvement characteristic of early sudden gains would be a better fit with the data above and beyond a linear trajectory. We expected that individuals in this study who experienced a sudden gain would have better clinical outcomes than those who did not. As BA involves behaviourally approaching uncomfortable and/or distressing stimuli, it is possible that it could produce depression spikes. We therefore explored whether a cubic pattern would provide a better fit to the data.

We also examined whether there were specific client processes associated with sudden gains and depression spikes. There is little research examining theoretically informed processes that may precede symptom change in treatments other than CBT, including BA. Although one study of BA found that baseline levels of dysfunctional cognition did not predict sudden gains (Hunnicutt-Ferguson et al. 2012), to our knowledge, there has been no

research examining whether factors that are postulated to be theoretically important to depression improvement in BA are associated with sudden gains or depression spikes. Behavioral Activation therapy is hypothesized to work by reducing avoidance and improving engagement with meaningful, reinforcing activities (Dimidjian et al. 2011; Martell et al. 2013). Because online treatments allow direct monitoring of the treatment material that participants are working on each week, we were able to examine the content that participants were engaged in prior to having a sudden gain session. For example, we could identify whether participants were still working on scheduling, or had moved to addressing dysfunctional patterns of behaviour using functional analytical techniques. We predicted that participants who made greater progress in their therapeutic content earlier in treatment and were directly addressing dysfunctional patterns of behaviours would be more likely to have a sudden gain.

Previous research has also found that stressful life events that either precede treatment or occur during treatment predict poorer outcomes (Monroe, Kupfer, & Frank, 1992). There has been a lack of research looking at the relationship between stressful life events that occur during treatment and sudden gains and depression spikes. We are aware of only one study – that study found that weekly self-reported stressful and positive events in a face-to-face community delivered CBT intervention did not differ between individuals who had a sudden gain or those who did not (Hardy, Cahill, Stiles, Ispan, Macaskill, et al. 2005). There have been no studies examining these factors in remotely delivered treatments. This is important because external client events such as stressful life events could inhibit sudden gains and drive depression spikes. We coded therapist reports of participant life events in the pre-gain and pre-spike sessions. We predicted that stressful life events would be associated with fewer sudden gains, more depression spikes and poorer outcomes.

We also aimed to examine therapist actions associated with sudden gains. Research using factor analysed subscales from the Collaborative Study Psychotherapy Rating Scale (CSPRS) in studies of CBT suggests that the extent to which therapists focus concretely and specifically on cognitive and/or behavioral strategies across sessions may predict greater overall patient symptom improvement (DeRubeis et al. 1990; Feeley, DeRubeis, and Gelfand, 1999). In this study, we directly coded therapist logs for descriptions of concreteness. We predicted that therapist-reported concrete behaviours in the session prior to the sudden gain would be associated with a sudden gain when compared to matched sessions in the non-sudden gain group. We also predicted that therapist-reported concrete behaviours would be associated with better depression outcomes at treatment end.

Lastly, we also examined whether baseline demographic and psychosocial characteristics were associated with sudden gains or depression spikes. It is unclear whether individuals who have sudden gains are simply higher functioning individuals who are better able to make use of treatment. Although previous research has shown that in-therapy changes in cognition, hope, or emotional expression are associated with sudden gains (Abel et al. 2016; Tang & DeRubeis, 1999; Tang, Luborsky, & Andrusyna, 2002), there has been little research that has investigated participant baseline characteristics. In an exception to this, Hunnicutt-Ferguson et al. (2012) found that neither baseline depression score nor dysfunctional cognitions predicted sudden gains. We examined predictors of sudden gains that have previously been shown to predict depression treatment outcome or were of theoretical interest to Behavioural Activation Treatment. These factors included: income level (Cort, Gamble, Smith, Chaudron, Lu, He, et al. 2012), functioning (Simon, 2000), perceived social support (Mynors-Wallis & Gath, 1997), and self-reported behavioral activation. We predicted that lower income level, functioning, social support and behavioral activation at baseline would be associated with fewer sudden gains.

Methods

Data Source: The Netmums Study

This study is a secondary analysis of data collected in the Netmums trial (O'Mahen et al. 2014). Netmums was a national (UK) randomized controlled trial that investigated the feasibility, acceptability and effectiveness of online BA for postpartum depression (PPD) plus treatment as usual (TAU) compared to TAU only. The Netmums trial was approved by the University of Exeter ethics committee.

Participants

Of the 249 individuals screened, 83 met the inclusion criteria and were randomized to either BA plus TAU (n=41) or TAU only (n=42) (see O'Mahen, Richards, Woodford, Wilkinson, McGinley et al. 2014 for CONSORT diagram and study details). The inclusion criteria were: women who were 18 years or older, had delivered a baby within the past year, and met criteria for diagnosis of depression according to ICD-10. If participants were taking antidepressants, they had to be taking a steady dose for at least two weeks. Potential participants were excluded if they were currently receiving mental health therapy. Because calculation of sudden gains/depression spikes requires calculating the means of the two (very early or late sudden gain or depression spike) sessions before or after the sudden gain or depression spike, we limited the sample in those calculations to those individuals who had at least three sessions (n=32/41, 78% of the sample).

Baseline Characteristics

Most women (90.2%, n=28/32) were married or living with a romantic partner and the median number of children was 2 (range 1-7). There was considerable range in income levels: 38.4% (n=8) had family incomes below £30,000; 36.4% (n=12) had family incomes between £30-60,000, and 25.2% (n=9) had family incomes of greater than £60,000. Educational attainment likewise varied: 41.4% (n=13) had less than an undergraduate degree;

56.1% (n=18) had an undergraduate or postgraduate degree. Most (80.5%, n = 26) women identified as being a "homemaker" or on maternity leave; 14.6% (n=5) reported they were studying or working full-time. Women identified themselves as primarily being White/British (92.6%, n=30). The baseline depression score (Edinburgh Postnatal Depression) was 20.24 (*SD* = 3.28). Over half the sample reported a previous history of mental health treatment: 65.9% (n=21/41) were taking antidepressants, for an average of 6.21 months (*SD* = 13.40, range 2 weeks to 60 months) and 36.6% (12/32) had sought outpatient mental health treatment at some time in the past year.

Therapy and Therapists

Participants were offered up to 12 sessions of online BA modified for perinatal content concerns (i.e., managing BA goals alongside infant needs). The treatment consisted of a core BA module (five sessions) that was followed by two optional modules from a list of a possible six (being a good enough mother, roles and relationships, communication, postnatal sleep, rumination, anxiety). The content included interactive exercises paired with extensive worked examples. The program was supported via telephone by one of two mental health workers, both of whom had undergraduate degrees and 1 year of further clinical qualification in psychological therapies under the UK Improving Access to Psychological Therapies (IAPT) training scheme. Therapists had previously been trained in monitoring and scheduling. In this trial therapists received an additional 5 days of training in functional analysis-based BA approaches and perinatal-specific content (Dimidjian et al. 2006; O'Mahen et al. 2014). Telephone sessions consisted of answering questions about treatment material and working through barriers to treatment implementation. Supporters followed a supporter-manual that outlined the structure and content of each session and common topics that participants might raise. The average length of a telephone session was 29 minutes (*SD* = 4.76) minutes. The first author, who is an experienced BA therapist and supervisor,

monitored therapist behavior against the supporter manual in a random selection of audio-taped sessions. Proscriptive behaviors (e.g., cognitive strategies, attachment-based approach) were addressed in supervision. Because treatment dose consisted of both completing online module content and engaging in telephone sessions with their therapists, we refer to completion of the online content as "module content" and contact with the therapist as "telephone session."

Measures

Depression Symptoms. The Edinburgh Postnatal Depression Inventory (EPDS; Cox et al. 1987) is a 10-item self-report measure assessing symptoms of depression in the postnatal period that was used at baseline and again at 17-weeks post-randomization. The EPDS has good internal reliability and good sensitivity and specificity (Gibson, McKenzie-McHarg, Shakespeare, Price & Gray, 2009). Participants also received computer prompts asking them to fill out the EPDS on a weekly basis.

Behavioral Activation. We used the 25-item Behavioral Activation for Depression Scale (BADS; Kanter et al., 2007) to assess behavioral activation over the past week. The BADS has good test–retest reliability (Kanter et al., 2007). Higher scores on the scale are indicative of more behavioral activation and less behavioral avoidance.

Social Support. We assessed perceived availability of support with the 24-item Social Provision Scale (SPS; Cutrona & Russell, 1987). The SPS has good reliability and validity and has been used widely in studies of social support. Higher scores represent greater perceived support.

Work and Social Functioning. We measured functional impairment with the Work and Social Adjustment Scale (WASAS; Mundt et al. 2002), a five-item measure that has demonstrated very good to excellent reliability and validity. The WASAS has been used with women suffering from postpartum depression (Reay et al. 2006).

Assessment of Treatment Content. Participants could take as many weeks as they wanted to complete a given treatment module. The amount of telephone based sessions, therefore, were unrelated to the module number that participants were working on (for example, a person could receive two telephone sessions for module 2). The online treatment program recorded the time and date participants logged on and off, and the treatment session they worked on. This information was used to determine the treatment content participants were working on in the session preceding the pre-sudden-gain session and at the height of the depression spike.

We also coded the therapist adherence logs. These were used both for recording content for research purposes and for use during clinical supervision. For each telephone session, therapists briefly described the content of each session, including what the session focused on, any barriers to working on material during or outside of session, and the homework assigned for the upcoming week. We assessed this content for: (1) whether the telephone session was spent working on specific, concrete treatment content (yes/no) (e.g., "identified [factors associated] with checking on baby, identified two alternative behaviors, determined to implement one over next week" versus "discussed incomplete monitoring sheet, participant upset and stressed, suggested trying monitoring sheet for another week," (2) stressful life events experienced by client that were a topic of therapy (yes/no; description of event; e.g., "participant's father ill, care is time-consuming"). If the client did not mention any stressful life events, or if those events were not a topic of therapy (e.g., occurred in the past, were life events that affected others but not the client) these sessions were coded as "no stressful event." To validate this coding approach, 5% of therapy tapes were randomly selected and independently coded for therapist concreteness. There was a high level of concordance, $r = .95$.

Calculating Sudden Gains and Depression Spikes

Sudden Gain. Tang and DeRubeis (1999) defined a sudden gain using three criteria. Firstly, the gain should be large in absolute terms. Tang and DeRubeis used a change of 7 points of more on the BDI. For other studies that have used different measures, a large change has been operationalized in terms of the reliable change index (Jacobson & Truax, 1991). We used the EPDS in this trial and used the Matthey (2004) definition of reliable change as a change of 4 points or greater. Secondly, the change should be should be large relative to the change in the previous session. We used Tang and DeRubeis (1999) criteria that the improvement was at least 25% of the score in the pre-gain session. Lastly, the sudden gain should represent a shift in scores that is larger than the stability of scores preceding and following the gain. Although Tang and DeRubeis originally defined this as a t-test comparing the three scores preceding the gain to the three scores following the gain, subsequent tests of sudden gains have conducted t-tests on the two scores preceding and following the sudden gain to allow examination of earlier sudden gains. We used this definition in this study. Importantly, some studies have failed to demonstrate that sudden gains are related to treatment outcome, although at least one of those studies examined a large drop in symptoms over a number of sessions (Vittengl et al. 2005), rather than a large drop in symptoms occurring between two sessions. Because the original Tang & DeRubeis time-frame criteria is both most consistent with the concept of a sudden gain, and there is evidence that it is more robustly associated with better short and long-term outcomes, we retained this criteria.

Depression Spike. The depression spike is, conceptually, the opposite of a sudden gain. Accordingly, we adapted the Hayes et al. (2007) definition of a depression spike to capture an absolute increase in depression scores that was consistent with the reliable change of 4 or greater on the EPDS, followed by a decrease of 4 points of more. In their study, Hayes et al. (2007) examined depression spikes using 7-point shifts on the Hamilton Rating Scale for Depression, and the increase and decrease in symptoms had to occur within a specific

phase of treatment. We expected that the spike would be most likely to occur when the individual was engaged in approach related behaviors that countered avoidance, and in BA these can occur at several points across the treatment. We therefore did not constrain the spike to a particular part of treatment. We did, however, examine only those spikes that occurred after session 3, when participants started to engage in approach- related behavior, and we specified that the spike should decrease by 4 points within 3 sessions. Thus, this operationalization of spikes is different from the Hayes et al. (2007) method, but is conceptually similar.

Sample Size Calculation

In a meta-analysis, Aderka and colleagues (2012) found sudden gains reliably predicted better treatment outcomes, with a moderate effect size (Hedges g = 0.62, 95% CI 0.43-.80). With one covariate, we needed a sample size of at least 30 participants in order to achieve 90% power, at .05 alpha.

In Hayes et al. (2007) study, depression spikes were related to a large difference in treatment outcome (Hedges's g = 1.16). With one covariate we needed a sample size of at least 12 to detect depression outcome differences between individuals who did or did not have a depression spike, controlling for depression score at baseline, at 90% power and .05 alpha.

Analytical Strategy

We first examined the shape of change in depressive symptoms (EPDS) using individual growth curve (IGC) modeling (Singer & Willett, 2003). There are problems with standard repeated-measures (i.e., ANCOVA, repeated measures ANOVA) approaches when using data with multiple assessment points across time. Standard repeated measures approaches assume that the timing between assessments will be equivalent and assume independence of observations. However, with multiple assessments there is the possibility

that there will be missing data, which violates the assumption of equal intervals between assessments. Further, with multiple repeated assessments (e.g., weekly mood measures), it is possible that each piece of information at each time point is not truly unique. This results in biased standard errors. An IGC approach is preferred to traditional repeated measures approaches because it reduces standard errors of within-subject change in the growth parameters estimates (Singer & Willett, 2003) and can more flexibly manage missing data and the associated problems this produces for the repeated measures assumption of equal intervals between assessments (Shek & Ma, 2011). Further, IGC approaches can consider the rate of change. It is also possible to examine whether the rate of change varies based on different predictors.

Using IGC, we examined whether the shape of symptom change followed a linear, quadratic, or cubic pattern and whether symptom severity at baseline affected the rate of change across individuals. This allowed us to test whether individuals who had more or less severe depressive symptoms varied in how well they responded to the treatment, across each of the three patterns of change.

We then conducted a second set of analyses that examined patterns of response within individuals. Using ANCOVA, we tested whether there were significantly significant differences between sudden gains and depression spikes (if there was a significant cubic pattern) on EPDS depression scores at 17-weeks post-randomisation, controlling for baseline (pre-randomisation) depression. We first used ANOVA to test for uncontrolled differences in between those with or without sudden gains or depression spikes and treatment adherence. Where there were significant differences, we subsequently used ANCOVA to determine if these differences remained after controlling for baseline EPDS depression scores. We conducted chi-square analyses to compare therapist reports of client stressful events and therapist concreteness and either sudden gains or depression spikes. We tested the

relationship between stressful life events and concrete therapist focus with ANOVA. Using logistic regression, we also examined whether baseline demographic and psychological variables predicted whether individuals had sudden gains or depression spikes after controlling for baseline EPDS depression scores. Where there were unequal sample sizes, we report the weighted mean.

Results

Shape of Change

In this study, we focused on the patterns of change in those in the treatment condition[1]. Using the intraclass correlation coefficient (ICC), we first assessed the proportion of outcome variation that was related to interindividual differences. The ICC was 11.08/(11.08 +14.78) = 0.43, suggesting that approximately 43% of the total variation in EPDS scores at 17-weeks post randomization was due to interindividual differences. An IGC approach is recommended when ICC values are 0.25 or greater (Shek & Ma, 2011).

We found that there was a significant linear decrease in EPDS depressive symptoms from a baseline mean of 18.11 (*SE* = 0.42) over time (β = -1.20, *SE* = 0.12, $p < .001$). The correlation (β = 0.86, *SE* = 0.34, $p = .01$) between the intercept and the linear growth parameter was positive, indicating that participants with higher EPDS baseline scores had a faster linear decrease.

We also tested a quadratic pattern of change. In this model, the growth parameters for initial status ($p < .01$), linear ($p < .01$) and quadratic ($p = .02$) trajectories were all significantly different from zero. The quadratic model improved model fit over the linear model ($\chi 2$ (1) = 2108.84 – 1021.43 = 1087.41, $p < .01$; Δ AIC = 2120.84 – 1035.84 = 1085.00; Δ BIC = 2144.53 – 1058.08 = 1086.45). The significant linear effect for EPDS depressive symptoms was negative (β = -3.60, *SE* = 0.86, $p < .01$), indicating that the rate of growth in depressive symptoms decreased over time. The significant quadratic effect was

positive (β = .73, *SE* = 0.31, *p* = .02, indicating that the rate of growth increased over time, although the rate of quadratic growth was slower (0.73) relative to the linear rate of change (-3.60). These results suggest that there was an initial, rapid decrease in symptoms, with a slowing down over time.

Lastly, we tested a cubic model of change. Although the linear (β = -2.82, *SE* = 0.58, *p* < .01), and quadratic (β = 0.43, *SE* = 0.18, *p* = 0.02) growth rates remained significant in that model, the cubic growth rate (β = 0.02, *SE* = 0.02, *p* =.14) was not significant. Further, the cubic model did not improve model fit over the quadratic model ($\chi 2$ (1) = 1021.43 – 1020.84 = 0.59 *p* < .44; Δ AIC = 1035.84 – 1036.84 = -1.0; Δ BIC = 1058.08 – 1062.73 = -4.65).

Sudden Gains

Of the total sample, 51% (n=18/32) had a sudden gain. Of those individuals who experienced a sudden gain, 33% (n=6/18) had more than one sudden gain. After controlling for baseline EPDS scores, ANCOVA analyses revealed that those in the sudden gain group (coded as 1) had fewer depressive symptoms at 17 weeks post-randomisation (M = 9.53, *SD* = 4.11) than those who did not have sudden gains, (coded as 0); *M* = 12.35, *SD* = 4.90), *F*(1, 34) = 4.46, *p* = 0.04. Cohen's *d* for this difference was 0.66, reflecting a medium effect size[2]. Although a higher percentage of women who had a sudden gain had clinical and reliable improvement in their depressive symptoms (55.55%, n=10/18), than women without a sudden gain (24%, n=4/17), this difference was not significant, X^2 (1)= .14, *p* = .71.

Depression Spikes

Of the total sample, only 19% (n=8) experienced a depression spike. The median pre-spike telephone session was session 5 (interquartile range: session 4 – session 8). The median pre-spike module completed was number 4 (interquartile range 1-7). Of the women who had a depression spike, 75% (n=6) also had a sudden gain. When participants had both a sudden

gain and depression spike, sudden gains preceded depression spikes in all but one participant. There were no differences in EPDS score at 17-week post-randomisation in those who did (*M* = 11.52, *SD* = 4.82) or did not (*M* = 12.38, *SD* = 4.96) have depression spikes *F (*1, 38) = 0.19, *p* = .73, η^2_p = 0.00. This difference equated to a small effect size (Cohen's d = 0.18). Because of the low frequency of depression spikes and because there was no overall cubic pattern of change, we did not conduct analyses examining predictors of depression spikes.

Client and Therapist Processes. Results of an ANCOVA revealed that although women with sudden gains had more telephone sessions with their therapists (*m* = 9.59, *SD* = 3.41) than women without sudden gains (*m* = 7.13, *SD* = 4.74), these differences were not statistically significant, *F* (1, 31) = 2.87, *p* =0.10, η^2_p = .09. The median pre-gain telephone session was session 3; 72% (n=13/18) experienced a sudden gain before telephone support session 5, which is equivalent to the 5th week of treatment.

Women who had a sudden gain did, however, complete more online modules (*m* = 7.35, *SD* = 43.90) than those without sudden gains (*m* = 4.26, *SD* = 3.75), *F* (1, 31) = 5.83, *p* = 0.02, η^2_p = 0.16). The median pre-gain module was 2.5 (2/3) (interquartile range = session 2 to session 4), the modal module was 2. Module 2 focussed on identifying patterns of avoidance, and module 3 addressed different approach related behaviours to replace the avoidance or maladaptive behaviour. In women who did not have a sudden gain, the median module women had completed by their 3rd telephone session (the median pre-gain telephone session) was module 1.5 (1/2) (interquartile range = session 1 to session 3), the modal module was 1 (see Table 1). Module 1 focussed on monitoring mood and behaviour in an effort to identify links between the two. We conducted an ANCOVA to assess whether sudden gains (yes/no) were associated with EPDS scores at 17-weeks post-randomisation after controlling for number of modules completed. In that model, neither number of modules completed *F (*1, 31) = 1.05, *p* = .32, η^2_p = 0.04 (corresponding to a small effect size), nor sudden gains, *F (*1,

399 31) = 1.85, p = .19, η^2_p = 0.06 (corresponding to a medium effect size; Cohen, 1988) were
400 significantly related to EPDS scores at 17-weeks post-randomisation.

401 Coded content from sessional therapist records indicated that individuals who had a
402 sudden gain were significantly less likely to have experienced a stressful life event during the
403 early stages of therapy than those who did not have a sudden gain, X^2 (1)= 8.48, p < .01.
404 Therapists also focussed on specific, concrete content more in the session preceding the
405 sudden gain than in the yoked sessions with women who did not have sudden gains, X^2 (1)=
406 9.03, p = .01. Fewer stressful life events and more concrete therapist focus were only
407 associated with having a sudden gain; they were not associated with EPDS mood at 17-weeks
408 post-randomisation. F (1, 31) = 3.46, p = .07, η^2_p = .11 (M stress=12.83, SD = 5.15, M less
409 stress = 9.85, SD = 4.24); F (1, 31) = 1.15, p = .33, η^2_p = .08, (M concrete = 12.33, SD =
410 4.76, M not concrete = 13.83, SD = 6.21).

411 Lastly, in logistic regression analyses, we assessed whether baseline demographic and
412 psychological characteristics predicted sudden gains (0,1) after controlling for baseline EPDS
413 score (see Table 3 for intercorrelations). Household income level, social support, work and
414 social functioning, and behavioral activation scores at baseline were not significantly related
415 to sudden gains (Table 4). In linear regression analyses, controlling for baseline EPDS score,
416 only baseline behavioral activation scores were associated with EPDS scores at 17 weeks
417 post-randomisation, β (2, 36) = 0.46, p = 0.03. Household income level, β (2, 36) = -0.09, p =
418 0.61, social support β (2, 36) = 0.10, p = 0.58, and work and social functioning scores, β (2,
419 36) = 0.07, p = 0.69 were not related to EPDS score at 17-weeks post-randomisation.

420 *Discussion*

421 In this study, we found that both a linear and a quadratic, but not a cubic, pattern
422 predicted change in an online BA treatment for women suffering from PPD. As predicted, the
423 quadratic pattern was the best fit with the data, suggesting an overall initial rapid decrease in

symptoms, followed by a deceleration in change. Individuals who had higher baseline levels of depression had a steeper decrease in depressive symptoms than women with lower baseline levels of depression. Consistent with this pattern of change, 51% of the women who received BA had a sudden gain, and the gains occurred early in treatment. In addition, those with sudden gains reported significantly fewer depressive symptoms at treatment end compared to those without sudden gains. Although more women who had sudden gains had clinically reliable reductions in their depressive symptoms than those who did not have sudden gains, this difference was not significant. This finding is in contrast to other studies of sudden gains, and may have been due to our smaller sample size.

These findings provide important information about when change occurs in an internet based BA treatment for depression. Even with less intensive forms of therapeutic support, such as those offered in internet-based treatments, sudden gains do occur, and they predict symptom outcome. Indeed, the 51% of women in this study who had a sudden gain is higher than the overall 36% of individuals who experienced a sudden gain in depressive symptoms during CBT based treatments in a recent meta-analysis (Aderka et al. 2013). Although we used a modified definition of sudden gains that allowed us to include earlier sudden gains, and this may have inflated the number of gains recorded, in their meta-analysis Aderka and colleagues (2013) found that type of sudden gain definition used between studies did not significantly alter either the number of gains identified or the effect of the sudden gain on outcome. It is as yet unclear whether the treatment we used in this study, BA, was responsible for producing a higher rate of sudden gains. Although at least one other study of BA has also reported a higher sudden gain rate of 42% (Masterson et al. 2014), another BA study reported a sudden gain rate of 35.7% (Hunnicutt-Ferguson et al. 2012). It is also possible that particular populations are especially responsive to BA. In this study, women with postnatal depression, who face intensive, immediate and consistent child care demands

were encouraged to focus on achieving meaningful balance in their activities (rather than activation per se), and to seek out appropriate support to help achieve balance. This focus may have produced a rapid decrease in symptoms associated with a reduction in caring burden. Such rapid improvements may be especially important in populations facing intensive demands by providing them with both the motivation and practical capacity to continue with treatment.

Overall, these results offer promising evidence that low-intensity, remotely delivered interventions can produce a rapid improvement in depression symptoms and that this change is associated with improvement at treatment end, consistent with Tang & DeRubeis' (1999) idea of an "upward spiral" in symptoms. Such findings are promising, given the global need to increase the accessibility and availability of psychological treatment and to reach populations that may, like postnatal women, face practical barriers to accessing traditional, face-to-face treatments. Longer-term follow-ups are needed to assess whether the relationship between sudden gains and outcome are sustained. However, these results provide initial support for the idea that low-intensity treatment formats may be "good enough" to produce the types of strong in-therapy shifts in mood that support later improved outcomes.

In contrast, we did not find that a cubic pattern of change that is characteristic of early sudden gains and later depression spikes fit the data. In our study, only 19% of women had a depression spike and depression spikes were not related to outcome. Although these findings may have been partly due to the lack of power associated with our sample size, the absolute numbers of individuals who had a depression spike was notably smaller than the 62% of individuals who experienced a depression spike in Hayes et al (2005) "exposure based CBT." Similarly, Pascual-Leone & Greenberg (2007) also reported increases in distress in the mid-phase of emotion-focused therapy for depression. Indeed, the small effect size we found for depression spikes (Cohen's d = 0.18) was considerably smaller than that reported

(Hedge's g = 1.16) in Hayes et al.'s (2005) study. However, Grosse-Holtforth et al. (2016) also found that depression spikes in the "traditional CBT" arm of their study were not related to lower depression scores at treatment end. Together with our findings, these results provide preliminary evidence that clinically helpful depression spikes may be unique to treatments that engage participants in intensive cognitive processing of depressogenic material. There has been little work to date that has directly compared depression spikes in behaviourally oriented and exposure based treatments. This work could help to elucidate whether depression spikes do vary between these treatments. Further, we because there is very little evidence in meta-analyses to suggest that bona-fide treatments differ in their overall efficacy (Cuijpers, van Straten, Andersson, & van Oppen, 2010), we suspect that if there are differences in depression spikes between these treatments, and if they affect outcome, then this may highlight important differences in both when and how these treatments work.

Client and Therapist Processes Associated with Sudden Gains. Importantly, in this study the online delivery format of the treatment allowed us to quantify the session content that women completed. We found that those who had sudden gains not only completed more treatment content overall across therapy, but they also established this pattern early on in treatment, completing more treatment content prior to the sudden gain session than women who did not have a sudden gain. Critically, this was not a mere effect of treatment dose in terms of sessions completed. There was no significant difference in the number of telephone sessions completed between women who did or did not have sudden gains. Women who had sudden gains had moved farther along with treatment content even though they had a similar number of telephone support sessions to women who had not had a sudden gain. In previous studies of sudden gains in BA, it has been unclear whether sudden gains were associated with monitoring and scheduling, which are present in both BA and CBT in the very early stages of treatment, or whether sudden gains were associated with addressing behavioral avoidance

patterns (e.g., avoidance, Hunnicutt-Ferguson et al. 2012; Masterson et al. 2014). In this study, all of the women who had a sudden gain had moved beyond monitoring and were working on content that addressed behavioral avoidance patterns. In contrast, women who did not have a sudden gain were most likely to still be working on content associated with monitoring in yoked pre-gain sessions. This was further supported by post-hoc content checks using the therapist records of the content discussed in session.

Participants in this study who had more life stressors were less likely to have a sudden gain than those with fewer life stressors. Although neither life stressors nor therapist behavior predicted symptom level at post-treatment follow-up, the effect sizes associated with these relationships suggest this may have been partly due to the size of the current sample. We note that in a previous study of face-to-face CBT, participant self-reported stressful and positive life events were not associated with sudden gains or outcome (Hardy et al. 2005). Although our findings are preliminary and limited by therapist rather than participant report of stressful life events, they point to the need in future research with larger samples to examine whether therapist actions in the face of external client events matter. For example, it may be important for therapists to take a concrete approach with clients who are encountering higher life stress. This is consistent with a body of work demonstrating that therapist competence and adherence interacts with client factors. For example, Strunk and colleagues (2010) found that therapist competence in CBT was more strongly related to outcome when the patient had co-morbid anxiety or an earlier age of depression onset, but not personality disorder. It may be especially important to examine therapist factors in the face of external client events in low-intensity and remote treatments relative to higher therapist contact treatments, such as the Hardy et al. (2005) study, as external client events may prove to be more “therapy interfering” without higher levels of support from competent therapists.

Our measured baseline characteristics, income, work and social functioning, behavioral activation, and perceived social support did not predict sudden gains. This is consistent with previous studies that have failed to find significant relationships between baseline characteristics and sudden gains (Hunnicutt-Ferguson et al. 2012). However, there may be indirect relationships between baseline characteristics and sudden gains that occur through other dimensions of therapeutic engagement, such as amount of therapeutic content completed. Indeed, we have reported elsewhere that baseline social functioning was related to number of modules completed in this sample (O'Mahen et al. 2013), and we found that number of modules completed was associated with sudden gains. This finding is further supported by a qualitative study of women who took part in a minimally supported online BA treatment for PPD; women who had poor practical social support and worse functioning reported that they struggled to engage with the treatment content (O'Mahen et al. 2015). Together, these results suggest that baseline characteristics may highlight "risk factors" for poor treatment engagement, which may be further moderated by therapist competence and adherence.

The results from this study also provide preliminary evidence that therapist factors processes may be related to sudden gains. Using coded therapist records, we found that a concrete therapist focus was associated with sudden gains. These results extend work from DeRubeis and colleagues (2010) who found clients had more symptom improvement from session 2 to 12 when therapists used more concrete CBT techniques, although they contrast with the lack of a relationship between concrete therapist style and sudden gains in Tang & DeRubeis (1999) study. Our study coded therapist behaviours from therapist records. This approach is limited in that therapists may not have accurately reported what they did in session, or may have missed out important information. Further, we did not formally assess whether therapists were adherent with the treatment protocol. It is therefore difficult to know

whether therapist results were due to their style, or the extent to which they were adhering to the treatment. It is also possible that therapists may have reported events in a more concrete style than they used in session, or vice versa. However, the approach we used built on the variability in the therapist's reports of the approaches they used. Further, when we randomly sampled 5% of the therapy tapes and coded them for concreteness, we found a high correlation with our codes and therapist reported behavior. Although future research is needed that directly codes therapist concrete behaviours from therapy sessions, the method we used here provides preliminary information about therapist factors. This approach may be especially useful in studies where there may be high levels of missing audio/visual data from therapy sessions.

Limitations and Future Directions

Although the small sample and follow-up in this study was largely consistent with other studies of sudden gains (Aderka et al., 2012, Hunnicutt-Ferguson et al., 2012, Masterston et al., 2014), we were limited in our ability to test for moderation, indirect relationships and the long-term effects of sudden gains by the sample size. Larger trials with longer follow-up periods are needed. However, many large trials do not gather the types of weekly assessments needed to test for patterns of change during treatment because they want to reduce participant burden and trial costs. The UK's "Improving Access to Psychological Therapies" successful large-scale implementation of empirically supported treatments has demonstrated the acceptability of gathering weekly mood symptom measurement (Clark, 2011). This will hopefully encourage researchers to obtain regular symptom assessments in future large-scale trials. Large-scale trials will allow tests of whether specific factors (e.g., client behavioral or cognitive change, therapist treatment specific adherence/competence) interact with non-specific processes (e.g., client life stress) to predict outcome, and whether

the timing of therapist and therapy (e.g., behavioral change strategy) factors matters between treatments, both in terms of short and long-term clinical outcomes.

Future studies would also benefit from multimodal assessment approaches, including client and therapist self-report of process variables and adherence and coded observational assessments, especially of the sessions immediately preceding and following points of change.

Although our sample was relatively unique amongst internet based studies for being socioeconomically diverse, it was also primarily White British. Rates of minority population engagement in both face-to-face and internet based treatments are low without additional supports put into place (O'Mahen, Himle, Fedock, Henshaw, & Flynn, 2013; Levy & O'Hara, 2010; Miranda, Azocar, Organista, Munoz, & Lieberman, 1996). It is critically important to conduct trials targeting methods that ensure minority population inclusion.

Our measure of depression spikes was adapted from Hayes et al. (2007), and we used a different measure of depression. These factors may have affected the number of women who met criteria for having a depression spike. We also note that the timing of depression spikes was earlier in this study than in other studies that have measured depression spikes. Studies like Hayes et al (2005; 2007) and Abel et al (2016) that coded client and therapist factors associated with depression spikes are needed to determine when spikes are related with intensive, purposeful client processing, or when they are temporary increases in depressive mood related to external stressful events. Overall, the very low number of women who had a depression spike affected our ability to meaningful assess whether spikes were related to outcome; larger trials are needed to determine when and if lower count experiences are clinically important and worthy of future study.

Conclusion

Our study adds to a growing body of literature demonstrating the clinical utility of identifying the course of change during therapy. To our knowledge, this is the first study reporting a quadratic pattern of change in a remotely delivered, low-intensity form of BA, which suggests early symptom relief and sudden gains. Our analysis of the sessions before sudden gains revealed that clients who experienced the sudden gain were addressing dysfunctional behavioral patterns compared to women who did not experience sudden gains, who were more likely to be focusing on monitoring or scheduling in the yoked pre-gain sessions. Further, therapists were more likely to use concrete techniques in the pre-gain sessions with women who had a sudden gain, especially when clients struggled with life stressors occurring early in therapy. These findings have implications for therapist training in BA, especially in regards to maintaining a concrete behavioral focus in response to client negative life events that occur during treatment. This may have particular benefits for low-intensity formats of treatments, where the amount of therapist contact time is often less than in high-intensity formats, increasing the need for supporters to be efficient and focused in their therapeutic approach.

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Table 1:

Pre-gain Module Content Women Were Working on by Sudden Gain/No Sudden Gain Group

Sudden Gain			No Sudden Gain		
Module	Frequency	Percent	Module	Frequency	Percent
1	0	0	1	8	50
2	9	5	2	5	31
3	3	16	3	3	19
4	2	11	4	0	0
5	2	11	5	0	0
6	2	11	6	0	0

Note.

Pre-gain sessions immediately precede a sudden gain (n-1). Participants typically completed the first five modules in sequential order: 1, Understanding depression and the mood-activity link; 2, How did I get here? Introduction to avoidance and functional analysis; 3, Help! I want to get better!' Introduction to planning Alternative meaningful behavior; 4, When the going gets tough. What to do. Contingency planning. Breaking down tasks and problem solving; 5, Getting the balance right. Being a mother and a person. Achieving TRACS in realistic ways. Participants then chose from amongst the optional modules: Being a good enough mothers, Support and communication, Changing roles and relationships, Sleep, Rumination, Anxiety.

Table 2:

Therapist Record of Specificity of Pre-Gain Session and Stressful Life Events by Sudden Gain/No Sudden Gain Group.

	Sudden Gain N(%)	No Sudden Gain N(%)	Total
Specific			
No mention of life event	9 (50)	2 (12)	11/24 (46)
Stressful life event	6 (34)	7 (41)	13/24 (54)
Total	15/18 (83)	9/17 (53)	
Not Specific			
No mention of life event	0 (0)	0 (0)	0/11 (0)
Stressful life events	3 (17)	8 (47)	11/11 (100)
Total	3/18 (17)	8/17 (47)	

[1] We had weekly EPDS data in the treatment condition only, so we were unable to examine shape of change, sudden gains, or spikes in TAU

Table 3

Intercorrelations Between Income Level, Social Support, Social Functioning, Behavioral Activation at Baseline and Depression Severity at 17 Weeks Post-Randomization.

	1	2	3	4	5
1. Income Level	-	.38**	-.00	.25*	-.16
2. Social Support		-	-.33**	.27*	-.31**
3. Social Functioning			-	-.50**	.04
4. Behavioral Activation				-	.08
5. Depression Severity (EPDS)					

Table 4.

Relationships between Income Level, Social Support, Social Functioning, Behavioral Activation and Sudden Gains Controlling for Baseline Depressive Symptoms (EPDS).

Model and variable	B	SE	Odds ratio	95% CI		p value
X^2 (1,5) = 2021, p = .82						
EPDS	.06	.14	1.06	.81	1.69	.68
Social Support	-.03	.05	.55	.89	1.06	.55
Social Functioning	-.17	.41	.85	.38	1.89	.68
Behavioral Activation	-.02	.02	.98	.94	1.03	.38
Income Level	.09	.13	1.09	.85	1.41	.49

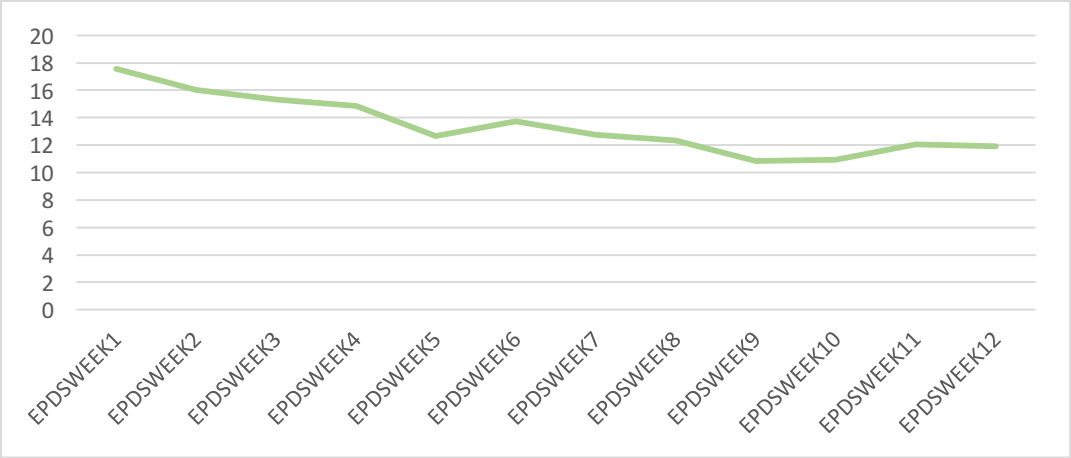

Figure 1. Average change in EPDS score by week

Highlights

- Examined shape of change, sudden gains and depression spikes in online treatment
- Quadratic shape of change best fit for online Behavioral Activation
- Sudden Gains but not depression spikes predicted more depression symptom reduction
- Client stressful life events and therapist concrete style related to sudden gains
- Therapy content finished but not amount of therapist contact related to sudden gain